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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,540	03/08/2001	Adrian Bot	A30571-A-PCT/USA-A	7183

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,540	BOT ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed March 8, 2001 is a continuation-in-part of application 09/308,511 filed May 19, 1999, which is a 371 national stage filing of PCT/US97/21687, filed November 21, 1997, which claims priority to application 08/755,034, filed November 22, 1996, now patent 6,204,250.

Applicants amendment filed April 13, 2006 has been received and entered. The specification has been amended. Claim 3 has been cancelled.

Claims 1 and 2 are pending.

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's after final amendment submission after final filed on April 13, 2006 has been entered.

Priority

As noted previously, the priority claim filed on August 29, 2005 has been entered and granted. See petition decision mailed October 3, 2005.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ali *et al.* (Infect Immun1982 Nov;38(2):610-9).

The instant claims encompass immunizing an infant broadly against any antigen and by any route of administration. No specific means of providing the nucleic acid encoding a relevant epitope is set forth in the claims, thus encompasses any delivery vehicle. In this case, a reasonable interpretation of the breadth of the claims would include the administration of an attenuated virus. An attenuated virus contains the nucleic acid that encodes relevant eptiopes which provides the basis of immunization to a subject.

Ali *et al.* teach and infant rat model where recombinant influenza viruses prepared from cold-adapted attenuated A/Ann Arbor/6/60 were used. Ali *et al.* demonstrate that administration of the attenuated virus resulted in immunization.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy *et al.* (J Clin Microbiol 1986 Aug;24(2):197-202).

As discussed above, a reasonable interpretation of the breadth of the instant claims would include the administration of an attenuated virus. Murphy *et al.* describe methods where both infants and children received inactivated respiratory syncytial virus vaccine. Murphy *et al.*

specifically describes the affect of these inoculations and the dissociation between serum neutralizing and glycoprotein antibody responses in the subjects.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricigliano *et al.* (US Patent 5,795,872) and Milagres *et al.* (Infect Immun 1994 Oct;62(10):4419-24).

The breadth of the claims is discussed above. Given the guidance of the present specification, an alternative embodiment encompassed by the claimed invention is the delivery of a DNA vaccine, that is the delivery of a recombinant nucleic acid that will encode an antigen for the immunization of an infant. At the time of filing DNA constructs and use of said constructs to express an antigen as a vaccine were known. Ricigliano *et al.* teach a specific DNA

construct for use in immunization (see allowed claims). Ricigliano *et al.* teach that nucleotide sequence of any antigen can be inserted into the construct, and provide methods where the DNA is delivered to the muscle resulting in expression and an immune response. Ricigliano *et al.* teach a variety of specific known antigens (claim 2 for example), however fail to specifically teach to immunize with antigens to *Neisseria meningitidis* nor specifically the immunization of infants. At the time of filing, Milagres *et al.* teach that the outer membrane protein of *Neisseria meningitidis* serves an appropriate and effective vaccine antigen in vaccinating infants from 3 to 83 months of age (see summary in abstract). At the time of filing immunization of infants for *Neisseria meningitidis* with subunit vaccines were known and practiced and the use of DNA vaccines provides a means to deliver such antigens to a subject. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use DNA constructs such as those provided in Ricigliano *et al.* for the use as a vaccine through the expression of protein antigens from *Neisseria meningitidis.* One having ordinary skill in the art would have been motivated to substitute the use of DNA vectors over conventional protein vaccines because of the limitations of providing a purified proteins and as a source of a more stable vaccine (i.e. DNA versus protein/attenuated virus). There would have been a reasonable expectation of success given the results of Milgres *et al.* for the immunization of infants to *Neisseria meningitidis* with a DNA vector as taught in Ricigliano *et al.* expressing a specific antigen such as the outer membrane protein of *Neisseria meningitidis* (Milgres *et al.*).

Thus, the claimed invention was *prima facie* obvious in the absence of evidence to the contrary.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fynan *et al.* (Proc Natl Acad Sci U S A 1993 Dec 15;90(24):11478-82) and Milagres *et al.* (Infect Immun 1994 Oct;62(10):4419-24).

As noted above, at the time of filing DNA constructs and use of said constructs to express an antigen as a vaccine were known. Fynan *et al.* teach a specific DNA construct for use in immunization (see allowed claims). Fynan *et al.* teach that nucleotide sequence of any antigen can be inserted into the construct, and provide methods where the DNA is delivered to the muscle resulting in expression and an immune response. Fynan *et al.* teach a variety of specific known antigens and different routes of administration, however fail to specifically teach to immunize with antigens to *Neisseria meningitidis* nor specifically the immunization of infants. At the time of filing, Milagres *et al.* teach that the outer membrane protein of *Neisseria meningitidis* serves an appropriate and effective vaccine antigen in vaccinating infants from 3 to 83 months of age (see summary in abstract). At the time of filing immunization of infants for *Neisseria meningitidis* with subunit vaccines were known and practiced and the use of DNA vaccines provides a means to deliver such antigens to a subject. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use DNA constructs such as those provided in Ricigliano *et al.* for the use as a vaccine through the expression of protein antigens from *Neisseria meningitidis.* One having ordinary skill in the art would have been motivated to substitute the use of DNA vectors over conventional protein vaccines because of the limitations of providing a purified proteins and as a source of a more stable vaccine (i.e. DNA versus protein/attenuated virus). There would have been a reasonable expectation of success given the results of Milgres *et al.* for the immunization of infants to

Neisseria meningitidis with a DNA vector as taught in Ricigliano *et al.* expressing a specific antigen such as the outer membrane protein of *Neisseria meningitidis* (Milgres *et al.*).

Thus, the claimed invention was *prima facie* obvious in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Oduntan et al. Ann Trop Med Parasitol.1978 Apr;72(2):111-5, The immunological response of Nigerian infants to attenuated and inactivated poliovaccines, provides further evidence that infants have been vaccinated with other types of attenuated viruses.

Montgomery *et al.* Curr Opin Biotechnol. 1994 Oct ;5(5):505-10; Protein expression *in vivo* by injection of polynucleotides, provides further evidence that the principle of DNA vaccines, expression of a protein upon injection of a polynucleotide were known at the time of filing.

Lagging *et al.* J Vir. 1995 Sept.:69(9):5859-5863, provides evidence that expression if antigens results in an immune response in an individual, and may serve as the basis of a vaccine.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 and 2 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-47 of copending Application No. 10/351,630. This is a double patenting rejection. In this case, the instant claims are drawn to immunizing an infant mammal against any target antigen, or more specifically a pathogen (claim 2) comprising inoculating the infant with an effective amount of a nucleic acid encoding a relevant epitope. The elected claims in '630 under examination encompass a bacterial antigen, however additional pending claims recite and encompass a wide range of various pathogens.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed. DNA vaccines were known at the time of filing (see for example Donnelly *et al.* 1994 (IDS reference)), and experiments demonstrated that nucleic acids encoding antigens could be administered as vaccines (see Donnelly *et al.* figure 1 for example (IDS reference)).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach